Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
Sent: 5/31/2017 2:03:49 PM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]
CC: Jakob, Avivah [Jakob.Avivah@epa.gov]; Cleland-Hamnett, Wendy [Cleland-Hamnett.Wendy@epa.gov]
Subject: RE: Question on Mosquitos

Rick-
How much sooner could an EUP be done? Are these ever done in a month?
When you take comment on the application, does mean that everything submitted is put in a docket and shared with the public?

Who is our contact at FDA if we wanted to transfer authority much sooner? I'd like to know the art of the possible if we wanted the transfer immediately. Oxitec would prefer if any field testing done this year were done under EPA not FDA and the Administrator would like us to be able to assist.

For section 3, assuming no SAP, what would be the fastest we could evaluate the data? Again, the Administrator is asking to understand why its 13 months and wondering if we can do it faster. I know its hard to speculate, but lets assume that Oxitec provides a good submission with everything we need on the first try.. (likely wishful thinking).

Thanks!

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From: Keigwin, Richard
Sent: Wednesday, May 31, 2017 9:09 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Here are some additional details, based upon an interagency meeting that happened a couple of weeks ago between Oxitec, FDA, EPA, and HHS.

Processing Time for an EUP
Under PRIA, the time allotted to complete an EUP review is 7 months. We have committed to issuing the EUP sooner than 7 months after receiving the application, however, how quickly we can complete the review depends, in part, on the completeness of the application. Also, because this would be an experimental use permit of "regional or national significance", under the regulations we are required to publish a notice of receipt of the EUP application and take comment on the application.

Transfer of Jurisdiction
Based upon the discussion at the interagency meeting with Intrexon/Oxitec, we are of the understanding that the company might be able start mosquito releases sooner under FDA's jurisdiction because we have determined that we need protein characterization data before moving forward with our review. The group discussed continuing to move forward with plans for a field trial under FDA's jurisdiction, while simultaneously submitting data to EPA that would

support EUP and/or Section 18 assessments needed to allow releases under EPA's oversight. The company and EPA agreed to expedite the scientific dialogue to get the needed data into EPA as soon as possible.

Oxitec suggested that a viable path would be where testing with field trials could occur under FDA oversight during the Summer/Fall of 2017 with an EPA EUP submission sometime in the Fall of 2017 and EUP issuance (and transfer of jurisdiction) occurring in February 2018 for field trial oversight in the Spring/Summer 2018 under an EPA EUP.

Section 3 Review Time

Under PRIA, the review time is approximately 13 months. This would include two comment periods: one upon receipt of the section 3 application and one at the end where we would propose a registration decision. I've been talking with the division director about whether we would need to have an SAP review before we completed our evaluation or after. With the plant-incorporated protectants, we have not had an SAP review prior to registration. For the Wolbachia mosquito that we will soon be proposing to register (hopefully this week), there has not been an SAP review. As with the EUP timeframe, in part, the timeframe depends upon the completeness of the application. Oxitec is preparing a crosswalk between the data they currently have available with our data requirements. Other than the protein characterization date, the efficacy data could be an issue. For Wolbachia, we are proposing to geographically restrict the registration, tailored the allowed use areas to match with the conditions under which the efficacy data were generated.

As always, let me know if you have any additional questions.

From: Beck, Nancy
Sent: Tuesday, May 30, 2017 2:42 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: Question on Mosquitos

Rick,
A few questions:

1) Are we closing the loop with FDA to see if they have any uses that would be interrupted by a transfer of authority to EPA? Is this something we should ask OGC to find out about or do you have the connections?
2) If oxitec were to submit an EUP, about how long do you think review would take? Oxitec says they heard 1 month then 7 months.
3) If oxitec were to submit a Section 3, for a conditional approval, about how long do you think review would take?

And of course, I understand that these are just estimates and it would depend on what they send us. Oxitec is saying that your folks have familiarity with the data from working with FDA on the issue.

Thanks!
Nancy

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